In the Claims

Pursuant to 37 C.F.R. §1.121(c)(1), please cancel claim 36 without disclaimer or prejudice to applicants' rights to pursue the subject matter of this claim in this or another application.

Additionally, please amend claims 1, 19, 25-31, 43, 50-54, 61 and 66 pursuant to 37 C.F.R. §1.121(c)(1) as amended by 68 Fed. Reg. 38611 (June 30, 2003) by replacing all prior versions of the claims with the listing of the claims as set forth below. The additions to the claims are indicated by underlining added material.

1. (Currently Amended) A pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of ~~Copolymer 1 (~~glatiramer acetate~~),~~ and an amount of microcrystalline cellulose in excess of 50 % by weight of the composition.

2. (Canceled)

3. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is at least 70 % by weight.

4. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 60% to about 90% by weight.

5. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 70% to about 80% by weight.

6. (Original) The pharmaceutical composition of claim 1,

wherein the microcrystalline cellulose has a moisture content of up to 5.0%.

7. (Original) The pharmaceutical composition of claim 1, wherein the microcrystalline cellulose has a moisture content of up to 1.5%.

8. (Original) The pharmaceutical composition of claim 1, further comprising a disintegrant.

9. (Original) The pharmaceutical composition of claim 8, wherein the disintegrant is selected from the group consisting of kaolin, starch, powdered sugar, sodium starch glycolate, crosscarmelose sodium, carboxymethyl cellulose, microcrystalline cellulose and sodium alginate.

10. (Original) The pharmaceutical composition of claim 9, wherein the disintegrant is a pregelatinized starch.

11. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 14%.

12. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 12%.

13. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 7%.

14. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 5%.

15. (Original) The pharmaceutical composition of claim 1, further comprising a lubricant.

16. (Original) The pharmaceutical composition of claim 15, wherein the lubricant is selected from the group

consisting of talc, sodium stearyl fumarate, magnesium stearate, calcium stearate, hydrogenated castor oil, hydrogenated soybean oil, and polyethylene glycol.

17. (Original) The pharmaceutical composition of claim 16, wherein the lubricant is magnesium stearate.

18. (Original) The pharmaceutical composition of claim 1, further comprising an enteric coating.

19. (Currently Amended) The pharmaceutical composition of ~~claim 1~~ claim 18, wherein the enteric coating is methacrylic acid copolymer.

20. (Original) The pharmaceutical composition of claim 18, wherein the enteric coating is selected from the group consisting of cellulose acetate phthalate (CAP), hydroxypropyl methyl cellulose phthalate (HPMCP), carboxymethyl ethyl cellulose (CMEC), or amino-alkylmethacrylate copolymer.

21. (Original) The pharmaceutical composition of claim 1, further comprising a film coating under the enteric coating.

22. (Original) The pharmaceutical composition of claim 21, wherein the film coating is selected from the group consisting of hydroxy propyl methyl cellulose (HPMC) and poly vinyl alcohol (PVA).

23. (Original) The pharmaceutical composition of claim 1 in solid form.

24. (Original) The pharmaceutical composition of claim 23, wherein the solid form is selected from the group consisting of a tablet, a hard gelatin capsule, a pellet and a particulate formulation.

25. (Currently Amended) The pharmaceutical composition of claim 24, wherein the solid form is a tablet and the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is from about 0.1 mg to about 300 mg.

26. (Currently Amended) The pharmaceutical composition of claim 25, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is from about 5 mg to about 100 mg.

27. (Currently Amended) The pharmaceutical composition of claim 25, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 5 mg.

28. (Currently Amended) The pharmaceutical composition of claim 25, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 50 mg.

29. (Currently Amended) A pharmaceutical composition in solid form comprising as an active ingredient a therapeutically effective amount of ~~Copolymer 1 (~~glatiramer acetate~~),~~ 70%-80% by weight of microcrystalline cellulose, and an enteric coating.

30. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 5 mg.

31. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 50 mg.

32. (Original) The pharmaceutical composition of claim 1, further comprising a pharmaceutically acceptable carrier suitable for application to mucosal linings, so as to thereby form a composition suitable for application to the mucosal linings of a subject.

33. (Original) The pharmaceutical composition of claim 32, wherein the carrier is chitosan.

34. (Original) The pharmaceutical composition of claim 33, further comprising a pharmaceutically effective amount of an anti-microbial preservative.

35. (Original) The pharmaceutical composition of claim 34, wherein the anti-microbial preservative is selected from the group consisting of sodium benzoate, methyl paraben, benzalkonium chloride, and propyl paraben.

36. (Canceled)

37. (Original) The pharmaceutical composition of claim 32, in dry powder form.

38. (Original) The pharmaceutical composition of claim 32, wherein the mucosal linings are bronchi-associated lymphoid tissue.

39. (Original) The pharmaceutical composition of claim 32, formulated for oral administration.

40. (Original) The pharmaceutical composition of claim 32, formulated for nasal administration.

41. (Original) The pharmaceutical composition of claim 32, formulated for pulmonary administration.

42. (Original) The pharmaceutical composition of claim 32, formulated for buccal administration.

43. (Currently Amended) A process for manufacturing the composition of claim 1, comprising:
a) milling the ~~Copolymer-1 (~~glatiramer acetate~~),~~

b) dry mixing the milled ~~Copolymer 1 (~~glatiramer acetate~~)~~ with at least 50% by weight of microcrystalline cellulose.

44. (Canceled)

45. (Canceled)

46. (Canceled)

47. (Canceled)

48. (Canceled)

49. (Canceled)

50. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is from about 5 mg to about 100 mg.

51. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 5 mg.

52. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is about 50 mg.

53. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is from about 0.01 mg/kg to about 2 mg/kg.

54. (Currently Amended) The pharmaceutical composition of claim 29, wherein the effective amount of ~~Copolymer 1 (~~glatiramer acetate~~)~~ is from about 0.05 mg/kg to about 1 mg/kg.

55. (Withdrawn) A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 50.

56. (Canceled)

57. (Canceled)

58. (Canceled)

59. (Canceled)

60. (Canceled)

61. (Currently Amended) The pharmaceutical composition of claim 1, further comprising a ~~protase~~ protease inhibitor.

62. (Previously Presented) The pharmaceutical composition of claim 3 in solid form.

63. (Previously Presented) The pharmaceutical composition of claim 62, wherein the solid form is selected from the group consisting of a tablet, a hard gelatin capsule, a pellet and a particulate formulation.

64. (Previously Presented) The process of claim 43, further comprising applying a film coating.

65. (Previously Presented) The process of claim 43, further comprising applying an enteric coating.

66. (Currently Amended) The process of ~~claim 45~~ claim 65, wherein the enteric coating is applied using a rotating pan system.

67. (New) A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 1.

68. (New) The method of claim 67, wherein said autoimmune disease is multiple sclerosis.

69. (New) The method of claim 67, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, GVHD and HVGD.

70. (New) The method of claim 55, wherein said autoimmune disease is multiple sclerosis.

71. (New) The method of claim 55, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, GVHD and HVGD.

72. (New) A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 53.

73. (New) The method of claim 72, wherein said autoimmune disease is multiple sclerosis.

74. (New) The method of claim 72, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, GVHD and HVGD.